L Number	Hits	Search T xt	DB	Time stamp
1	52184	diab tes r diabetic or "syndr m x" or "m tab lic syndrom " or "insulin r sistanc syndrom "	USPAT; US-PGPUB; DERWENT	2003/03/13 11:53
5	6206	t piramat r sulfamat r sulphamat	USPAT; US-PGPUB; DERWENT	2003/03/13 11:54
9	13	(diabetes or diabetic or "syndrome x" or "metabolic syndrome" or "insulin resistance syndrome") same (topiramate or sulfamate or sulphamate)	USPAT; US-PGPUB; DERWENT	2003/03/13 11:54

The R.W. Johnson Pharmaceutical Research Institute Announces Results Of Studies With Topiramate in Diabetic Neuropathic Pain

Raritan, NJ (September 17, 2001) - The R.W. Johnson Pharmaceutical Research Institute (RWJPRI), a subsidiary of Johnson & Johnson, has completed evaluation of the results of three pivotal clinical trials conducted with topiramate in patients with diabetic neuropathy. In each trial, topiramate failed to demonstrate a statistically significant difference in efficacy compared with placebo in the targeted primary efficacy endpoint. The clinical trials also showed that topiramate was generally well tolerated, and there were no unexpected safety findings.

Based on these findings, the R.W. Johnson Pharmaceutical Research Institute does not plan to pursue an indication for diabetic neuropathic pain with topiramate at this time, and the R.W. Johnson Pharmaceutical Research Institute open-label extension phase of these trials will be discontinued.

Ortho-McNeil Pharmaceutical, Inc., also a Johnson & Johnson company, is conducting the remaining trial of topiramate in diabetic neuropathic pain. That trial, which is nearing completion, is designed differently than the R.W. Johnson Pharmaceutical Research Institute trials. Since safety concerns have not been identified with the R.W. Johnson Pharmaceutical Research Institute trials, the Ortho-McNeil study will be completed.

Topiramate is currently marketed under the brand name TOPAMAX® in the U.S. by Ortho-McNeil, and elsewhere in the world by other Johnson & Johnson affiliates.

Clinical studies are underway to determine the safety and efficacy of topiramate in the treatment of bipolar disorder and obesity, and for the prevention of migraine headaches.

TOPAMAX® is indicated as adjunctive therapy for adults and pediatric patients ages two-16 years with partial onset seizures or primary generalized tonic-clonic seizures, and in patients two years of age and older with seizures associated with Lennox-Gastaut syndrome. In clinical trials for these indications, the most common side effects observed in children included excessive drowsiness, loss of appetite, fatigue, nervousness, difficulty with concentration/attention, weight loss, aggressive reaction and memory difficulties. In adults, the most common types of side effects were sleepiness, dizziness, poor coordination, speech difficulties, slowed thinking (psychomotor slowing), blurred or double vision, memory difficulties and changes in sensation. However, these effects were generally temporary.

Topiramate is available in tablets and in capsules that can be opened and sprinkled onto food for easy swallowing. The capsules also can be swallowed whole, offering patients greater flexibility.

Based in Raritan, New Jersey, R.W. Johnson Pharmaceutical Research Institute conducts pharmaceutical research and development for the pharmaceutical companies of Johnson & Johnson. Information about TOPAMAX® can be found at www.topamax.com. Information about other Ortho-McNeil products can be found on the Internet at www.ortho-mcneil.com.

This news release contains 'forward looking statements' as defined in the US Private Securities Litigation Reform Act of 1995. These statements are based on current expectations of future events. If underlying assumptions prove inaccurate or unknown risks or uncertainties materialize, actual results could vary materially from the Company's expectations and projections. Risks and uncertainties include general industry conditions and competition; economic conditions such as interest rate and currency exchange rate fluctuations; technological advances and patents attained by competitors; challenges inherent in new product development including obtaining regulatory approval; US domestic and international health care reforms and governmental laws and regulations; and trends toward healthcare costs containment. A further list and description of these risks, uncertainties and other factors can be found in US Exhibit 99(b) of the Company's Annual Report on US Form 10-K for the fiscal year ended December 31, 2000. Copies of this Form 10-K are available online at www.sec.gov or on request from the Company. The Company assumes no obligation to update any forward-looking statements as a result of new information or future events or developments.

# # #

THIRD INTERNATIONAL CONFERENCE ON BIPOLAR DISORDER

Poster Abstracts

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Learning Disabilities And Bipolar Spectrum Disorders

*M.G. Carta, *M.C. Hardoy, °M.J. Hardoy *Institute of Psychiatry, University of Cagliari, Italy °Psychiatric Unit, University of Florence, Italy

Several studies indicate that psychiatric disorders are more frequent in people affected with mental retardation (MR) than in the general population. Bipolar spectrum disorders, as many different authors think, are evident examples of underestimated disorders in patients affected with MR. A review of the literature based on case reports and open trials will be reported. The actual state of knowledge seems to suggest the usefulness of mood stabilizers in bipolar syndromes in subjects with MR. Yet, sufficient evidence of their efficacy is lacking. The future RCT need to take into account the disorders that underlay MR and consider adequate stratifications. Moreover the study discusses the difficult applicability of rigid diagnostic psychiatric categories for future research on MR.

Elevated Frequency of Diabetes Mellitus in Bipolar Disorder

F. Cassidy, E.P. Ahearn, B.J. Carroll Duke University, Durham, N.C., U.S.A.

Although high medical comobidity has been sometimes suggested to occur in psychiatric patients, little attention has been given to the occurrence of diabetes mellitus in bipolar disorder. In the current abstract we present preliminary results testing whether the rate of comorbid diabetes in a manic population is higher than that expected based on national norms.

Medical histories were reviewed in 345 patients, age 20-70, admitted to John Umstead Hospital, Butner, N.C. who met DSM-IIIR criteria for Bipolar Disorder, manic (n=309) or mixed (n=48), for a previous diagnosis of diabetes mellitus. Thirty-six of 345 patients (10.1%) had previously been given a diagnosis of diabetes mellitus. The overall national prevalence of diagnosed diabetes mellitus is 3.4%. Rates of diabetes mellitus increase with age, and have also been suggested to be higher in blacks compared with whites, and in females compared with males. Constructing a weighted mean for age (categorized by ten year intervals), sex and race from these national norms we determined an expected prevalence of 3.5% diabetes in our sample. The actual number of patients in the cohort previously having a comorbid diagnosis of diabetes mellitus (36) was significantly greater than the number expected from national norms (12 of 345, c 2 =10.271, p<.002).

Psychiatric histories were available for twenty-nine of the thirty-six diabetic manics. These twenty-nine patients were age-matched to five years with non-diabetic manics. Mean ages of the two groups, diagnostic subtype, sex and race were not statistically different between the groups. Histories were

compared using Wilcoxon signed ranks tests and a Bonferroni correction applied to the significance levels. Age of first psychiatric hospitalization did not differ between the groups, however the total number of lifetime psychiatric hospitalizations in the diabetic manic group (10.9 S.D. 10.5) was significantly greater than in the non-diabetic manic group (5.3 S.D. 5.2, z=-2.261, p<.05).

Do Symptom Profiles and Subtypes Remain Stable Across Manic and Mixed Episodes of Bipolar Disorder?

F. Cassidy, E.P.Ahearn, B.J. Carroll Duke University, Durham, N.C., U.S.A.

Few studies have compared the symptom presentation across discrete manic or mixed episodes in manic depressive patients. In the current abstract we compare 104 diagnostic evaluations completed during two hospitalizations in 52 patients meeting DSM-IIIR criteria for Bipolar Disorder, manic or mixed. The diagnostic subtype (manic vs. mixed) was determined using both DSM-IIIR criteria and new proposed criteria requiring the presence of 2 or more of 6 dysphoric manic symptoms (depressed mood, anhedonia, guilt, suicidality, fatigue, anxiety). Episodes were also evaluated using the Scale for Manic States (1) and subscale scores compared. The statistically determined subscales are arithmetic sums of the relevant scale items and represent dysphoria, psychomotor activation, psychosis, hedonic drive, and irritable aggression (2). Categorical data were compared using Fisher exact tests and factor scores compared with Pearson correlation coefficients with a Bonferroni correction. Results follow:

DSM IIIR	manic episode 2	mixed episode 2	Proposed Definition	manic episode 2	mixed episode 2
manic episode 1	45	4	manic episode 1	34	8
mixed episode 1	2	1	mixed episode 1	3	7
	non-significant			p=.003	

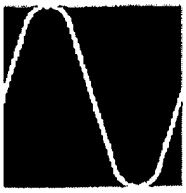
Factors:				
Dysphoria	Psychomotor Activation	Psychosis	Hedonic Drive	Irritable Aggression
r=.515, p<.001	r=.023, n.s.	r=.440, p<.01	r=.524, p<.001	r=.560, p<.001

Using DSM-IIIR criteria for Bipolar Disorder, mixed, only 8 of 104 episodes were categorized as mixed and no relationship between episodes was demonstrated. Using the new definition, the presentation of mixed episodes in individuals was not purely random. Nevertheless considerable variability occurs between episodes.

Cassidy F, Murry E, Forest K, Carroll BJ. Signs and Symptoms of Mania in Pure and Mixed Episodes. J Affect Disorders, in press.
Cassidy F, Forest K, Murry E, Carroll BJ. A Factor Analysis of the Signs and Symptoms of Mania. Arch Gen Psych 1998;55:27-32.

A Family Study f Suicidal Behavior in Bipolar-Spectrum Disorders

P. Cavazzoni, University of Ottawa, Department of Psychiatry, Ottawa, Canada; P. Grof, University of Ottawa, Department of Psychiatry, Ottawa, Canada; A. Duffy, University of Ottawa, Department of Psychiatry, Ottawa, Canada; E. Grof, University of Ottawa, Department of Psychiatry, Ottawa,



THIRD INTERNATIONAL CONFERENCE ON BIPOLAR DISORDER

Schedule

DAY 1: THURSDAY, JUNE 17, 1999

MORNING

7:45 a.m.	**Registration and Continental Breakfast**
8:30 a.m.	**Background** David J. Kupfer, M.D.

Session I: "Treatment of Bipolar Depression: A Review of New Approaches"
Chair: Ellen Frank, Ph.D.

8:45 a.m.	"Interpersonal and Social Rhythm Therapy Prevents Depressive Symptomatology in Bipolar I Patients" Ellen Frank, Ph.D.
9:05 a.m.	"Multifamily Group Treatment for Bipolar Depression" Gabor I. Keitner, M.D.
9:25 a.m.	"Treatment of Bipolar Depression" Gary S. Sachs, M.D.
9:45 a.m.	**Panel Discussion**
10:00 a.m.	**Break**

Session II: "Epidemiology/Comorbidity"
Chair: Kathleen R. Merikangas, Ph.D.

10:15 a.m.	"Epidemiology of Bipolar Spectrum Disorder in Community Based Studies" Jules Angst, M.D.
10:35 a.m.	"Comorbidity of Migraine and Affective Disorders" Kathleen R. Merikangas, Ph.D.
10:55 a.m.	"Bipolar Disorder during Adolescence and Young Adulthood in a Community Sample" Peter M. Lewinsohn, Ph.D.
11:15 a.m.	"Personality Disorder or Bipolar Illness: New Thoughts" Robert M.A. Hirschfeld, M.D.
11:45 a.m.	**Panel Discussion**
12:00 Noon	**Lunch (on your own)**

AFTERNOON

Session III: "Neuroscience and Neuroimaging"
Chairs: Husseini K. Manji, M.D., F.R.C.P. and Perry F. Renshaw, M.D.,

Ph.D.

1:00 p.m.	**"Recent Status of Genetic Studies in Bipolar Disorder"** Steven M. Paul, M.D.
1:30 p.m.	**"Signaling Pathways and Gene Expression: Molecular Mechanisms Underlying Mood Stabilization in the Brain"** Husseini K. Manji, M.D., F.R.C.P.
2:00 p.m.	**"Regulation of Gene Expression in the CNS: *FosB: A Molecular Mediator of Long-term Neural Plasticity"** Eric J. Nestler, M.D., Ph.D.
2:30 p.m.	**Break**
2:45 p.m.	**"Magnetic Resonance Spectroscopy and Functional Magnetic Resonance Imaging"** Perry F. Renshaw, M.D., Ph.D.
3:15 p.m.	**"Current Status of MR Studies in Bipolar Disorder"** Gregory J. Moore, Ph.D.
3:45 p.m.	**"fMRI Studies of Affect Recognition in Healthy Adolescents and Adults with Bipolar Disorder"** Deborah Yurgelun-Todd, Ph.D.
4:15 p.m.	**Panel Discussion**
4:45 p.m.	**Adjournment**
5:00 p.m.	**Poster Session**
7:00 p.m.- 9:00 p.m.	**Reception - The Grand Concourse Restaurant**

DAY 2: FRIDAY, JUNE 18, 1999

MORNING

7:45 a.m.	**Registration and Continental Breakfast**
8:30 a.m.	**Background** Ellen Frank, Ph.D.

Session IV: "Impact of Select Conditions on the Treatment of Bipolar Disorder"
Chair: Michael E. Thase, M.D.

8:45 a.m.	**"The Use of Medications in Bipolar Women during Pregnancy and Postpartum"** Lori Altshuler, M.D.
9:15 a.m.	**"Complex Bipolarity: Temperament, Anxious Comorbidity and Mixed States"** Hagop S. Akiskal, M.D.
9:45 a.m.	**Break**
10:00 a.m.	**"Impact of Substance Abuse on the Cours and Treatment of Bipolar Disorder"** Michael E. Thase, M.D.

10:30 a.m. **Panel Discussion**

11:00 a.m. **Meeting to Establish International Society for Bipolar Disorders**

11:45 a.m. **Lunch (on your own)**

AFTERNOON

1:00 p.m. **Interactive Sessions: Ask the Experts**

1. "Comorbidity and Its Clinical Relevance for Bipolar Spectrum Disorders"
Giovanni B. Cassano, M.D.

2. "Diagnostic and Biological Aspects of Treatment Specificity in Bipolar Disorders"
Alan G. Mallinger, M.D. and Jair C. Soares, M.D.

3. "Agitated Depression"
Athanasio Koukopoulos, M.D.

4. "Differentiating among Multiple Treatment Opportunities for Bipolar Depression"
William Z. Potter, M.D., Ph.D.

2:00 p.m. **Break**

AFTERNOON

Session V: "New Pharmacotherapies"
Chair: Fouzia Laghrissi-Thode, M.D.

2:15 p.m. **"Methodological Issues and Practical Difficulties in Conducting Clinical Trials in Bipolar Disorder"**
John A. Ascher, M.D.

2:45 p.m. **"Combination Treatment in Bipolar Disorder"**
Atul Pande, M.D., F.R.C.P.C.

3:15 p.m. **Break**

3:30 p.m. **"Novel Endpoints for Clinical Trials in Bipolar Disorder"**
Fouzia Laghrissi-Thode, M.D.

4:00 p.m. **"Use of Antipsychotics in Bipolar Disorder"**
Mauricio Tohen, M.D., Dr.P.H.

4:30 p.m. **Panel Discussion**

5:00 p.m. **Adjournment**

5:00 p.m. **Poster Session**

7:00 p.m. **Cocktails - The Carnegie Museums of Pittsburgh**

8:00 p.m. **Dinner - The Carnegie Museums of Pittsburgh**

"Present and Future Role of Advocacy Associations in the Management of the Mentally Ill: Needs, Myths, Realities and Hopes at the Edge of the Third Millennium"

Speaker: Paolo Lucio Morselli, M.D.
Vice President, IDEA
Secretary General, GAMION

DAY 3: SATURDAY, JUNE 19, 1999

MORNING

7:45 a.m.	**Registration and Continental Breakfast**
8:30 a.m.	**Background** Michael E. Thase, M.D.

Session VI: "Suicide"
Chair: Kay Jamison, Ph.D.

8:45 a.m.	**"Genetics of Suicide"** Sylvia G. Simpson, M.D.
9:05 a.m.	**"Neuropathology of Suicide"** Susan E. Bachus, Ph.D.
9:25 a.m.	**"Reduced Risk of Suicidal Behavior in Bipolar Disorder Patients during Long-term Treatment with Lithium"** Ross J. Baldessarini, M.D.
9:45 a.m.	**Panel Discussion**
10:00 a.m.	**Break**

Session VII: "Access, Services, and Health Policy Issues"
Chair: Kelly J. Kelleher, M.D., M.P.H.

10:15 a.m.	**"Principles of Population-Based Care of Patients with Bipolar Disorder"** Michael Von Korff, Sc.D.
10:35 a.m.	**"Clinician Incentives for Improving Quality"** Howard Goldman, M.D., Ph.D.
10:55 a.m.	**"VA Cooperative Study #430: Reducing the Efficacy-Effectiveness Gap in Bipolar Disorder"** Mark Bauer, M.D.
11:15 a.m.	**Panel Discussion**
11:30 a.m.	**Lunch (on your own)**

Day 3: Saturday, June 19, 1999

AFTERNOON

1:00 p.m. **Interactive Sessions: Ask the Experts**

A. "Risk Factors"
Paula J. Clayton, M.D.

B. "Bipolar Disorder and Suicid "
Jan A. Fawcett, M.D.

C. "Family Issues"
David Miklowitz, Ph.D.

D. "Medication Guidelines and Patient Education for Patients with Bipolar Disorder"
Trisha Suppes, M.D., Ph.D.

E. "Clinical-Legal Issues: Work Disability, Criminal Responsibility, and Civil Responsibility"
Robert M. Wettstein, M.D.

2:15 p.m. **Break**

2:30 p.m. **Family Psychoeducational Workshop**

Family/Consumer Track

Steve S. Carter, Ph.D.
Daniel P. Cole, M.D.
Holly Swartz, M.D.
Steven J. Verfaille, L.S.W.
Lee K. Wolfson, M.Ed.

Provider Track

Debra Frankel, L.S.W.
Alan G. Mallinger, M.D.
Noreen Reilly-Harrington, Ph.D.

4:30 p.m. **Adjournment**

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